

## PATIENT INFORMATION LEAFLET

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# FemSeven® Sequi

(estradiol hemihydrate/levonorgestrel)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### In this leaflet:

1. What FemSeven Sequi, patch is and what it is used for
2. What you need to know before you use FemSeven Sequi, patch
3. How to use FemSeven Sequi, patch
4. Possible side effects
5. How to store FemSeven Sequi, patch
6. Contents of the pack and other information

### 1. What FemSeven Sequi, patch is and what it is used for

FemSeven Sequi is a Hormone Replacement Therapy (HRT). It contains two types of female hormones, an oestrogen (estradiol) and a progestogen (levonorgestrel). FemSeven Sequi is used in postmenopausal women.

FemSeven Sequi is used for:

#### Relief of symptoms occurring after menopause

During the menopause, the amount of the oestrogen produced by a woman’s body drops. This can cause symptoms such as hot face, neck and chest (“hot flushes”). FemSeven Sequi alleviates these symptoms after menopause. You will only be prescribed FemSeven Sequi if your symptoms seriously hinder your daily life. FemSeven Sequi The experience treating women above the age of 65 is limited.

### 2. What you need to know before you use FemSeven Sequi, patch

#### Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family’s medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on FemSeven Sequi you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with FemSeven Sequi.

Go for regular breast screening, as recommended by your doctor.

### Do not use FEMSEVEN® SEQUI, patch

If any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before taking FemSeven Sequi. Do not take FemSeven Sequi:

- If you have or have ever had **breast cancer**, or if you are suspected of having it;
- If you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it;
- If you have any **unexplained vaginal bleeding**;
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated;
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism);
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency);
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**;
- If you have or have ever had a liver disease and your liver function tests have not returned to normal;
- If you have a rare blood problem called “porphyria” which is passed down in families (inherited);
- If you are **allergic** to estradiol or levonorgestrel or any of the other ingredients of this medicine FemSeven Sequi (listed in section 6).

If any of the above conditions appear for the first time while taking FemSeven Sequi, stop taking it at once and consult your doctor immediately.

### When to take special care with FemSeven Sequi, patch

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with FemSeven Sequi. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb;
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia);
- increased risk of developing blood clots (see “Blood clots in a vein (thrombosis)”);
- increased risk of getting a oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer);
- high blood pressure;
- a liver disorder, such as a benign liver tumour;
- diabetes;
- gallstones;
- migraine or severe headaches;
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE);
- epilepsy;
- asthma;
- a disease affecting the eardrum and hearing (otosclerosis);
- a very high level of fat in your blood (triglycerides);
- fluid retention due to cardiac or kidney problems;
- hereditary and acquired angioedema.

### Stop using FemSeven Sequi and see a doctor immediately

If you notice any of the following when taking HRT:

- any of the conditions mentioned in the ‘Do not use FemSeven Sequi, patch’ section;
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease;
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema;
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness);
- migraine-like headaches which happen for the first time;
- if you become pregnant;
- if you notice signs of a blood clot, such as:
  - painful swelling and redness of the legs;
  - sudden chest pain;
  - difficulty in breathing.

For more information, see ‘Blood clots in a vein (thrombosis)’

*Note: FemSeven Sequi is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.*

### HRT and cancer

#### Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer).

Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

The progestogen in FemSeven Sequi protects you from this extra risk.

#### Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking FemSeven Sequi. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:

- carries on for more than the first 6 months;
  - starts after you have been using FemSeven Sequi more than 6 months;
  - carries on after you have stopped using FemSeven Sequi;
- see your doctor as soon as possible.**

#### Breast cancer:

Evidence shows that taking combined oestrogen-progestogen and or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Contact your doctor if you notice changes to your breasts, such as: dimpling of the breast, skin changes in the nipple, lumps that you can see or feel.

Your doctor may advice you to undergo a check up including mammography.

#### Compare

Looking at women aged 50 to 54 who are not taking HRT, on average 13 to 17 in 1000 will be diagnosed with breast cancer over a 5 year period. For women aged 50 who start taking oestrogen-only HRT for 5 years, there will be 16-17 cases in 1000 users (i.e. an extra 0 to 3 cases). For women aged 50 - who start taking oestrogen progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases). Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period. For women aged 50 who start taking oestrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases) For women aged 50 who start taking oestrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. an extra 21 cases).

#### • Regularly check your breasts. See your doctor if you notice any changes such as:

- dimpling of the skin;
- changes in the nipple;
- any lumps you can see or feel.

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

#### Ovarian cancer:

Ovarian cancer is rare - much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5- year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

#### Effects of HRT on heart and circulation Blood clots in a vein (thrombosis):

The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery);
  - you are seriously overweight (BMI >30 kg/m2);
  - you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots;
  - if any of your close relatives has ever had a blood clot in the leg, lung or another organ;
  - you have systemic lupus erythematosus (SLE);
  - you have cancer.
- For signs of a blood clot, see “Stop using FemSeven Sequi and see a doctor immediately”

#### Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e.an extra 5 cases).

#### Heart disease (heart attack)

There is no evidence that HRT will prevent a heart disease.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

#### Stroke

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

#### Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

#### Other conditions:

- HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

#### Other medicines and FemSeven Sequi, patch

Some medicines may interfere with the effect of FemSeven Sequi. This might lead to irregular bleeding. This applies to the following medicine: FemSeven Sequi:

- medicines for epilepsy (such as phenobarbital, phenytoin and carbamazepin),
- medicines for tuberculosis (such as rifampicin, rifabutin),
- medicines for HIV infection (such as nevirapine, efavirenz, ritonavir and nelfinavir),
- herbal remedies containing St. John’s Wort (*Hypericum perforatum*).

HRT can affect the way some other medicines work:

- A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures
- Medicines for Hepatitis C virus (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as a regimen with glecaprevir/pibrentasvir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. FemSeven contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using FemSeven with this HCV combination regimen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

#### Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are using FemSeven Sequi, because this medicine can affect the results of some tests.

#### Pregnancy and breast-feeding

FemSeven Sequi is for use in postmenopausal women only. If you become pregnant, stop using FemSeven Sequi and contact your doctor.

#### Driving and using machines

No specific side effect is expected.

### 3. How to use FemSeven Sequi, patch

Always use this medicine FemSeven Sequi exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

You should apply the patch once a week i.e. replace it every 7 days without a break in treatment: as soon as you remove one patch, you should apply another one to your skin.

There are 2 types of patches in the box, depending on when you apply one:

- Phase 1 patches (1st and 2nd weeks of your cycle): they contain only one active substance (Estradiol).
  - Phase 2 patches (3rd and 4th weeks of your cycle): they contain both active substances (Estradiol and Levonorgestrel).
- If you are not taking HRT or you switch from a continuous combined HRT product, treatment may be started on any convenient day. If you are transferring from a sequential HRT regimen, treatment should begin the day following completion of the prior regimen.

#### Frequency of application:

1. Apply a Phase 1 patch once a week for the first 2 weeks of your cycle.
  2. Remove the Phase 1 patch and apply a Phase 2 patch, once a week for the following 2 weeks.
- You must apply the patches in the correct order.

Bleeding similar to periods usually occurs at the end of the use of the Phase 2 patches. The bleeding is light and lasts for 4 to 5 days on average.

If the bleeding is heavy or irregular, consult your doctor.

#### Method of administration

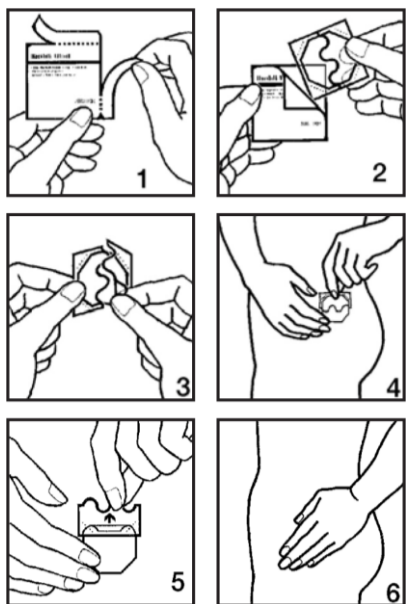
This medicine should be applied to the skin.

#### How to apply a patch?

Each sachet contains one patch. FemSeven Sequi must be applied immediately after being removed from its sachet.

1. To open the sachet, tear the two edges in the direction of the arrow.
2. Remove the patch from the sachet. A patch has two sections: the patch itself, which must be applied to the skin, and the protective liner.
3. Remove one-half of the liner, starting at the S-shaped notch and taking care not to touch the adhesive side of the patch with your fingers. If you do, it may not adhere correctly and you may alter the active ingredients.
4. Apply the patch immediately, using the palm of your hand, to a dry, clean area of skin. It should not be red or covered with cream or lotion. The location should not have any significant wrinkles and it should not be rubbed by clothing (avoid placing at the waist and do not wear very tight clothing). The patch may be applied, for example, to the buttocks, thighs, abdomen etc.

- Remove the other part of the plastic liner and press down on the corresponding area of the patch.
- Keep the palm of your hand on the patch for at least 30 seconds to ensure that it is adhering correctly, especially round the edges. The pressure and heat of the hand are essential to ensure maximum adhesion.



#### How to remove the patch?

To remove a FemSeven Sequi, simply free up one edge and pull it off gently so as not to irritate the skin. If any of the adhesive remains on the skin, you can remove it by rubbing the skin gently with a cream or an oily lotion.

After use, the patch still contains active substances, but in too small a quantity for it to remain effective. Fold the patch in half (adhesive to adhesive) before discarding it.

#### Precautions for use

Do not apply a FemSeven Sequi patch:

- to your breasts.
- Twice in the same place: leave at least 1 week between 2 applications in the same place.

#### During the course of treatment:

- You must not expose the patch directly to the sun once you have applied it to your skin.
- You can shower or take a bath with the patch on your skin.
- If the patch becomes unstuck before the end of its use i.e. before the 7th day (for example if you have undertaken intense physical effort or perspire abundantly or the skin is rubbed by clothes), use a new patch (from the same phase) and remove it at the initially scheduled date.

#### Duration of treatment

Your doctor will decide on the duration of treatment. Contact your doctor if you want to stop the treatment.

#### If you take more FemSeven Sequi than you should

Overdose is unlikely but it can cause the following:

- pain in the breasts,
- bloating in the abdomen, flatulence, nausea and vomiting,
- irritability, anxiety,
- vaginal bleeding.

No specific treatment is required. The signs will disappear when the patch is removed.

#### If you forget to take FemSeven Sequi, patch

- If you have forgotten to change the patch on the scheduled day, replace it immediately then follow the treatment normally, changing the patch again on the initially scheduled day.
  - Do not use 2 patches at the same time to make up for the single dose that you have forgotten.
  - If you have not used FemSeven Sequi for several successive days, you may get stop bleeding.
- If you are in doubt, consult your doctor.

#### If you stop using FemSeven Sequi, patch

The postmenopausal signs linked to a lack of oestrogen may reappear.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### If you need to have surgery

If you are going to have surgery, tell the surgeon that you are using FemSeven Sequi. You may need to stop using FemSeven Sequi about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start using FemSeven Sequi again.

#### 4. Possible side effects

Like all medicines, this medicine FemSeven Sequi can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:

- breast cancer;
  - abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer);
  - ovarian cancer;
  - blood clots in the veins of the legs or lungs (venous thromboembolism);
  - heart disease;
  - stroke;
  - probable memory loss if HRT is started over the age of 65;
- For more information about these side effects, see Section 2.

#### The following side effects may occur the most frequently (in more than 1 in 10 patients treated).

- Skin reaction (itching, irritation, redness) in the area in which the patch is applied. These signs are not serious and usually disappear 2 or 3 days after removing the patch. If they persist, place the patch in a different area.

#### The following side effects may occur frequently (in 1 to 10 people in 100):

- Tightness or pain in the breasts.
- Headaches.
- Nausea, vomiting.
- Irregular bleeding, spotting
- Increase or decrease in sexual desire.

#### The following potential side effects are less frequent (in 1 to 10 people in 1,000):

- Benign breast tumour.
- Painful periods.
- Abnormal development of the lining of the uterus (endometrial hyperplasia).
- High blood pressure.
- Bloating or pain in the abdomen.
- Fatigue.
- Weight gain or loss.
- Migraine.
- Vertigo.
- Cramp in the legs.
- Swelling (water retention, oedema).

#### The following side effects may occur but are rare (1 to 10 people in 10,000):

- Yellowing of the skin and whites of the eye (jaundice).
- Benign tumour in the uterus (uterine fibroma).
- Gall stones
- Depression.

The following side effects have been reported with other HRTs:

- gall bladder disease
- various skin disorders:
  - discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma);
  - painful reddish skin nodules (erythema nodosum);
  - rash with target-shaped reddening or sores (erythema multiforme).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store FemSeven Sequi

- Keep out of the sight and reach of children.
- Do not store FemSeven Sequi transdermal patches above 30°C.
- Keep your medicine in sachets they come in until just before you need each one.
- Do not use patches after the expiry date on the pack. Take unused patches or patches that have passed their expiry date to the pharmacist for disposal.
- Do not use a FemSeven Sequi if you notice any visible signs of deterioration of the patch.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What FemSeven Sequi contains

The pack contains two types of patches:

**Phase 1:** Each patch contains 1.5 mg of estradiol hemihydrate in a patch size of 15 cm<sup>2</sup>, releasing 50 micrograms of estradiol per 24 hours.

**Phase 2:** Each patch contains 1.5 mg of estradiol hemihydrate and 1.5 mg of levonorgestrel in a patch size of 15 cm<sup>2</sup>, releasing 50 micrograms of estradiol and 10 micrograms of levonorgestrel per 24 hours.

The inactive ingredients are transparent polyethylene terephthalate foil, styrene-isoprene-styrene block copolymer, glycerine esters of hydrogenated resin acids and the removable siliconised transparent polyethylene terephthalate foil.

##### What FemSeven Sequi looks like and contents of the pack

FemSeven Sequi patches are octagonal, transparent, flexible patches with rounded edges.

Each patch is coated with adhesive and is mounted on an oversized, removable, protective liner.

The adhesive is made of a mixture of polymer and modified resin containing the active ingredients.

Each pack contains four (2 x Phase 1 and 2 x Phase 2) to provide you with one month's treatment.

##### Manufacturer and product licence holder

FemSeven Sequi is manufactured by Teva Pharmaceuticals Europe B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands. Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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